Volume III Issue 18
October 2013

POSTSCRIPTS

In this issue:

Official publication of the American Medical Writers Association Pacific-Southwest Chapter

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of Postscripts is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, Postscripts publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of the members, Postscripts includes news and event notices covering Chapter activities.

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SUBSCRIPTION

Postscripts is published monthly except in January and July. Subscription is included in the AMWA Pac-SW chapter membership which is automatic for all AMWA members with a mailing address in Southern California, Southern Nevada and all of Arizona. This newsmagazine is distributed on the 1st of each month. AMWA members can request past issues by sending an email to the editor.

INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike. Please contact editor.

ADVERTISING

Articles describing products and services relevant to medical writers may be considered or solicited. Members may submit advertisements for their services or products for free. Please contact editor for details.

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(AMWA Pac-SW)
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POSTSCRIPTS

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UPCOMING EVENTS AND DATES

October 5, 2013: Peggy Wallace – Interview Tricks and Tips, Carlsbad-by-the-Sea, CA
November 6-9, 2013: AMWA Annual Conference, Columbus, OH
November 17, 2013: Donna Simcoe – Publication Planning, a tcon/webinar presentation.
December 7, 2013: Holiday gathering – Jacki Dyck-Jones, Thousand Oaks, CA.

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COVER: Bike path near Ghirardelli square by Ajay Malik

From the President's Desk

Jenny is out attending to more pressing committments. . .
She will be back next month.

Office. By doctor_bob, Morguefile.com; wildfire image from www.rfs.nsw.gov.au

Spotlight on CMPP

By Jennifer Reichert, PhD, CMPP

In March of this year I became a Certified Medical Publication Professional (CMPP). I have been a practicing medical publication professional for several years, so I thought it would be worthwhile to take the time to become "certified." I was right. The certification process was stimulating and rewarding. Certification allowed me to participate in a process which measures the unique skill set and knowledge base of our profession. Preparing for and taking the exam reinforced for me the values of our profession. The CMPP credential also brings recognition to other professions that we as publication professionals measure and certify the skills and knowledge of our profession.

The CMPP credential is an exam-based credential sponsored by the International Society of Medical Publication Professionals (ISMPP). It was established in 2009 to certify

- Expertise as a medical publication professional
- Proficiency in good publication practices
- Commitment to ethical and transparent data dissemination standards
- Leadership in upholding and fostering integrity and excellence in medical publication

The CMPP program provides a formal credential of our expertise and promotes integrity and excellence in the profession by demonstrating knowledge of, and encouraging adherence to, best-practices across the industry.

The exam is offered two times per year at testing facilities around the world. Taking the three-hour online exam was a stimulating experience. The exam tested my knowledge of authorship guidelines, publication ethics, good publication practices, publication planning, development and implementation, and professional responsibilities.

In order to be eligible to take the exam, a publication professional must have been working in publication planning for 2-5 years. The credential is appropriate for medical writers, publication planners, editors, medical affairs planners, regulatory writers and planners.
There are currently 726 CMPPs.

More information can be found at http://www.ismpp.org/cmpp.

What's Up(!) . . . at FDA

By Sally Altman and Kelly Dolezal

During the past month, the FDA prohibited manufacture of food and drug products from six companies. The agency announced a new guidance and rule for medical products, partnered with the NIH to create a new tobacco research center, and updated safety labeling for opioids.

FDA Announcements

9-23-13	The FDA provided guidance on mobile medical apps to protect patients while encouraging innovation. One app that is currently on the market, and which will receive FDA oversight under the new guidance, can detect abnormal heart rhythms via a smartphone.[1]
9-20-13	U.S. Marshalls seized food products from two Virginia companies, Gourmet Provisions, LLC and Royal Cup, Inc. following sanitation violations due to rodent and insect infestations.[2]
9-20-13	The FDA finalized its new rule for unique medical device identification (UDI). A unique number will now be assigned to each device by the manufacturer, which can be publicly searched in the Global Unique Device Identification Database (GUDID). [3]
9-19-13	The FDA and NIH have partnered to create the Tobacco Centers of Regulatory Science (TCORS) to provide science-based regulation of tobacco products. TCORS has seven research areas, including reducing addiction, toxicity and carcinogenicity, and marketing.[4]
9-18-13	A consent decree of permanent injunction was issued to Shamrock Medical Solutions Group in Ohio, which repeatedly failed to follow CGMP labeling practices for non-sterile medications.[5]
9-16-13	The FDA prohibited manufacture and import of products from Ranbaxy Laboratories, Ltd. in India due to CGMP violations during manufacturing and data integrity issues.[6]
9-10-13	The FDA updated safety labeling for extended-release, long-acting (ER/LA) opioids. Products must now indicate use of ER/LA opioids for only those patients for whom alternative treatment is inadequate, and contain a warning that chronic maternal use of ER/LA opioids can lead to neonatal opioid withdrawal syndrome (NOWS). [7]
9-6-13	A consent decree was issued against T&T Cattle and T&T Cattle Pearl in Idaho after cows with elevated levels of penicillin and sulfadimethoxine were offered for slaughter. Previous investigations noted the failure to keep proper medication records for treated cattle.[8]
9-3-13	A consent decree was issued against Dakota Laboratories LLC after repeated CGMP violations.[9]

For additional information, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm.

1 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369431.htm [Link]
2 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369381.htm [Link]
3 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369276.htm [Link]
4 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368992.htm [Link]
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6 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368445.htm [Link]
7 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm [Link]
8 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367493.htm [Link]
9 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367097.htm [Link]

What's Up(!) . . . at EMA

By Wim D'Haeze

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (26 AUG 2013 THROUGH 24 SEP 2013)

The alerts listed below cover the period from August 26, 2013 through September 24, 2013. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to What's New on the EMA website.

GUIDELINES

• None to rreport

REPORTS/PAPERS

• Conflicts of Interests – At a glance: An overview of the European Medicines Agency's policy on conflicts of interests for scientific committee members and experts[a]

APPROVALS/REFUSALS

Compound	Indication/Use	Applicant	Advice [Note]
Lidocaine/ Prilocaine Plethora[b]	Treatment of primary premature ejaculation in adult men.	Plethora Solutions Ltd	Positive opinion
Relvar Ellipta[c]	Treatment of asthma in adults and adolescents aged 12 years old and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. Symptomatic treatment of adults with COPD with a FEV1 < 70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.	Glaxo Group Ltd	Positive opinion
Kadcyla[d]	treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.	Roche Registration Ltd.	Positive opinion
Abilify Maintena[e]	Maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.	Otsuka Pharmaceutical Europe Ltd.	Positive opinion
Memantine Accord[f]	Treatment of patients with moderate to severe Alzheimer's disease.	Accord Healthcare Ltd.	Positive opinion
Xofigo[g]	Treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.	Bayer Pharma AG	Positive opinion
Invokana[h]	Treatment of adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control.	Janssen-Cilag International N.V.	Positive opinion
Levodopa Carbidopa Entacapone Sandoz[i]	Treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations not stabilised on levodopa/dopa decarboxylase (DDC) inhibitor treatment.	Orion Corporation	Positive opinion

(continued on next page)

Fluenz Tetra[j]	Prophylaxis of influenza in children and adolescents 24 months to less than 18 years of age. The use of Fluenz Tetra should be based on official recommendations.	MedImmune LLC	Positive opinion
NovoEight[k]	Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).	Novonordisk	Positive opinion
Vitekta[l]	Co-administered with ritonavir-boosted protease inhibitor and with other antiretroviral agents, for the treatment of HIV-1 infection in adults who are infected with HIV-1 without known mutations associated with resistance to elvitegravir.	Gilead Sciences International Ltd.	Positive opinion

Note: “positive” or “negative” opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC)

GENERAL ANNOUNCEMENTS

• European Medicines Agency reveals new structure.[m]

LINKS

EMA Website - What's New: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/whats_new.jsp&mid=WC0b01ac058004d5c4 [Link]

[a].http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500148661 [Link]

[b].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002693/smops/Positive/human_smop_000589.jsp&mid=WC0b01ac058001d127 [Link]

[c].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002673/smops/Positive/human_smop_000591.jsp&mid=WC0b01ac058001d127 [Link]

[d].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002389/smops/Positive/human_smop_000597.jsp&mid=WC0b01ac058001d127 [Link]

[e].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002755/smops/Positive/human_smop_000593.jsp&mid=WC0b01ac058001d127 [Link]

[f].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002766/smops/Positive/human_smop_000586.jsp&mid=WC0b01ac058001d127 [Link]

[g].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002653/smops/Positive/human_smop_000585.jsp&mid=WC0b01ac058001d127 [Link]

[h].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002649/smops/Positive/human_smop_000596.jsp&mid=WC0b01ac058001d127 [Link]

[i].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002785/smops/Positive/human_smop_000588.jsp&mid=WC0b01ac058001d127 [Link]

[j].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002617/smops/Positive/human_smop_000594.jsp&mid=WC0b01ac058001d127 [Link]

[k].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002719/smops/Positive/human_smop_000587.jsp&mid=WC0b01ac058001d127 [Link]

[l].http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002577/smops/Positive/human_smop_000592.jsp&mid=WC0b01ac058001d127 [Link]

[m].http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/09/news_detail_001886.jsp&mid=WC0b01ac058004d5c1 [Link]

Upcoming AMWA-PacSW Event - October 5, 2013

Interview Tips and Techniques: Creating personal strengths stories to persuade the Interviewer to become YOUR ADVOCATE!

By Peggy Wallace, Making Conversation LLC
peggy@makingconversation.com

Peggy Wallace, founder in 2004 of Making Conversation, is a graduate of University of Pennsylvania/Wharton School and Boston University School of Law. With over 25 years business experience as a corporate attorney (major financial institutions), fundraiser (GIA) and financial services sales consultant (Merrill Lynch), Peggy has a first-hand appreciation of the value of making conversation, while being authentic and enthusiastically showing one's own unique personality, opening doors by winning with words. Peggy's Interview Preparation emphasizes conveying your talking points or message through memorable strengths stories. Clear, concise, persuasive and relevant personal stories demonstrate your individual strengths so the interviewer becomes your advocate.

Peggy has made presentations to a broad variety of scientists (AWIS; Burnham; Salk; LIAI; TRSI; UCSD), post-docs, graduate and undergraduate students. Peggy was part of a California Endowment Grant to UCSD's School of Medicine teaching interview skills to potential medical school applicants. She has worked with applicants from ages 12-65 for internships, jobs, scholarships and admission to high school, college and graduate schools.

Peggy will be making a presentaion to the AMWA Pac-SW members on October 5, 2013 at Carlsbad-by-the-Sea retirement community in Carlsbad. Check your mailbox for announcement from Jenny Grodberg regarding registration instructions.

Meanwhile, check out her blog at http://makingconversationwebsite.blogspot.com/ In a recent email to those on her mailing list, she reminds these wise words:

- "By failing to prepare, you are preparing to fail." Benjamin Franklin
- "I will prepare and some day my chance will come." Abraham Lincoln
- "I believe luck is preparation meeting opportunity. If you hadn't been prepared when the opportunity came along, you wouldn't have been lucky." Oprah Winfrey

AGENDA:

11:30 - 12:00	Registration/Networking
12:00-12:45	Lunch
12:45-1:00	Chapter Announcements
1:00-1:05	Biobreak
1:05-2:05	Presentation
2:05 - 2:20	Additional Q&A
2:20	Closing

AMA-zing Style — the AMA Manual of Style Column

By Dikran Toroser, PhD, Amgen Inc.

ACKNOWLEDGEMENTS & DISCLOSURES

The Acknowledgement section of a manuscript represents an important repository for some vital information. Conflicts-of-interest disclosures are examples of such information—and in the fast changing publications environment, these are under particular scrutiny. The AMA manual is a useful primer for this subject and contains some useful information under the following subheadings:

Financial Disclosure. *JAMA* and the *Archives* Journals require authors to sign and submit a financial disclosure statement. The statement may cover affiliations with or financial involvement within the past 5 years and foreseeable future with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the publication.

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> Additional Contributions: William Wise PhD, Dynapharm Inc, contributed to the writing of this article; and Sarah Jewel MA, Medical Writers Corp, helped edit the initial manuscript.

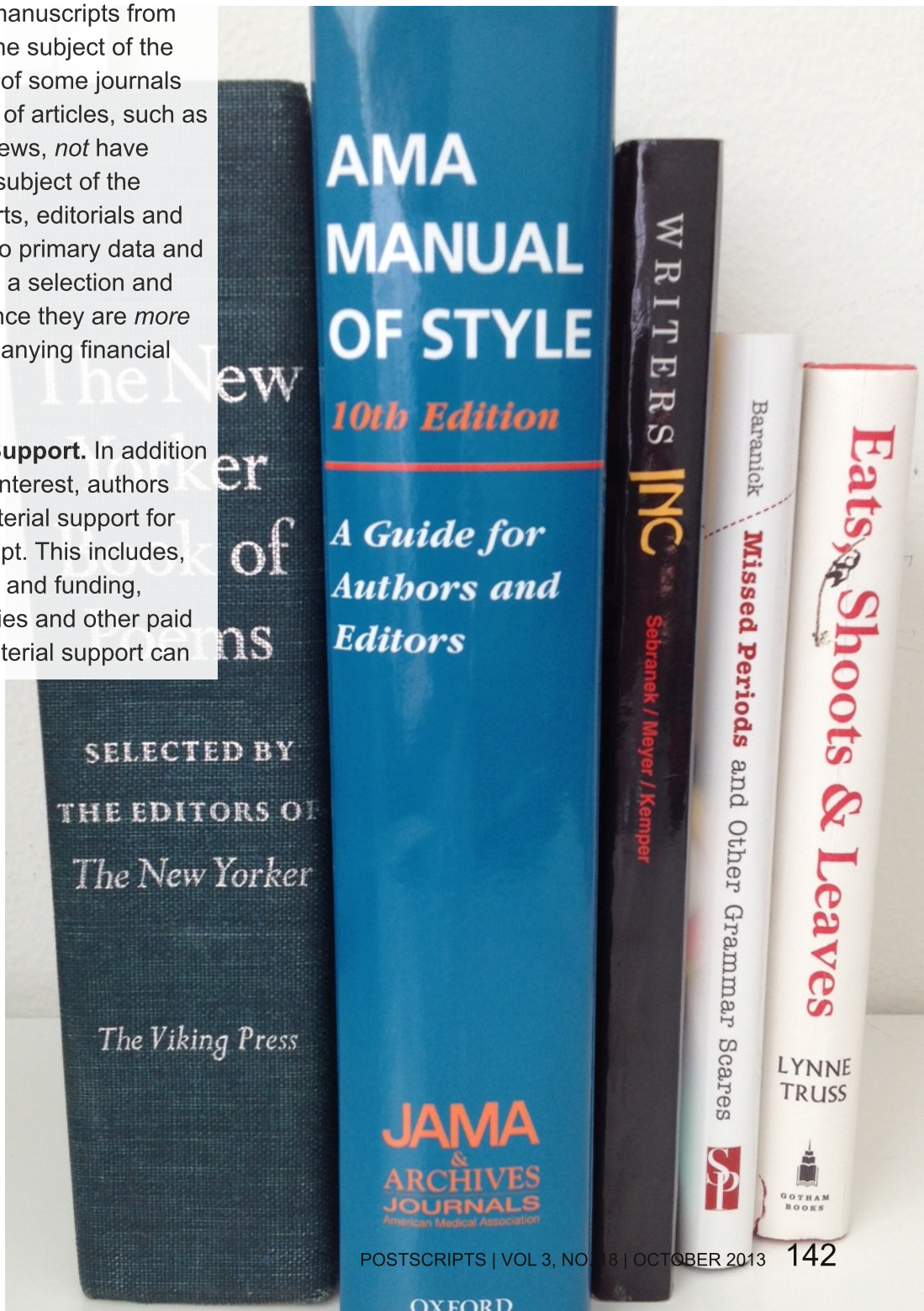
(continued on next page)

Access to Data Requirement. The *ICMJE* recommends that journals ask authors of studies funded by an entity with a proprietary or financial interest in the outcome of the study to sign a statement attesting that they had full access to the data and take responsibility for the integrity of the data and accuracy of the analysis. The *ICMJE* recommends that editors publish authors' conflict of interest statements if they believe that the information will help readers.

Some journals might not accept manuscripts from authors with financial interest in the subject of the manuscript. For example, editors of some journals prefer that authors of some types of articles, such as editorials, commentaries and reviews, *not* have relevant financial interests in the subject of the manuscript. Unlike scientific reports, editorials and non-systematic reviews contain no primary data and offer an evaluation of a topic from a selection and interpretation of the literature; hence they are *more* susceptible to bias which accompanying financial disclosures may not prevent.

Reporting Funding and Other Support. In addition to individual financial conflicts of interest, authors should report all financial and material support for the work reported in the manuscript. This includes, but is not limited to, grant support and funding, provision of equipment and supplies and other paid contributions. All financial and material support can be indicated in the Acknowledgment section of the manuscript, along with information on the roles of each funding source or sponsor. In addition, all individuals who provided other important paid contributions should be identified, with their names and affiliations listed in the Acknowledgment section of the manuscript, or as authors if they meet the full criteria for authorship.

Further details can be found in the AMA Manual of Style 10th edition.



de-MS-tifying Word

By Susan Chang, PhD, Susan Chang Consulting
and Alyssa Wu-Zhang, PhD

Are you still entering multiple hard returns and manual page breaks to create optimal spacing of text, tables, and figures? Please have a seat for this formatting intervention…

BREAKING THE HARD-RETURN HABIT

¶ ← Let's discuss why we don't want to see this in your formatted document.

¶ MS Word has multiple paragraph formatting features that allow you to control placement ¶ of text, tables, and figures without using numerous hard returns, which can create ¶ unwanted blank space and odd placement of document components if text shifts even ¶ slightly. And if you're a medical writer, text often shifts more than slightly!

THE FAB FOUR FORMATTING FEATURES

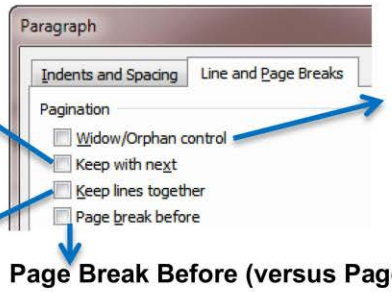
The four features outlined below allow you to maintain the preferred positioning of document elements without redoing page breaks every time text is revised. They can be applied manually as needed or built into your predefined Styles. Just right-click on the line where you want to apply the paragraph formatting and choose Paragraph → Line and Page Breaks tab. Alternatively:

PC (Word 2007+): Home tab → Paragraph dialog box launcher → Line and Page Breaks tab

Mac (Word 2010): Format menu → Paragraph... (launches dialog box) → Line and Page Breaks tab

Keep With Next:

Section, table, and figure titles should not stand alone at the bottom of a page. Apply "Keep With Next" to prevent this. The line that should be shifted to the next page is the only line that needs to have this feature applied.



Widow/Orphan Control:

In most cases, a single line of text should not be left alone at the bottom or top of a page. Widow/Orphan Control is a setting that helps prevent this. It is generally safe to keep this box checked.

Keep Lines Together:

When several lines of text should be kept together (ie, should not break across a page), apply "Keep Lines Together." Apply this feature to all the lines of text that should stay together. Sometimes this also works for rows of a table, but many times "Keep With Next" may need to be applied to all the rows as well.

Let's Stay Together…

To force an entire paragraph and its heading to stay together on one page, apply "Keep With Next" to the paragraph heading and "Keep Lines Together" to the paragraph text.

Page Break Before (versus Page Break):

Text, table, and figure placement can be controlled using "Window/Orphan Control," "Keep With Next," and "Keep Lines Together" in most cases; however, sometimes a forced break in pagination may be needed.

Applying "Page Break Before" means that the page break is associated with the paragraph formatting. You will not see this mark, which is only for manual page breaks:

Page Break ¶

- If the main sections of a document should always begin on a new page, "Page Break Before" should be applied to the heading of the section.
- If you want to force a section heading onto a new page for spacing purposes, but it is not always required, it's more efficient to use the "Keep With Next" option instead of repeatedly revising the placement of manual page breaks.

TIP: When paragraph marks ¶ are shown, you will see this mark ▪ to the left side of the text if any of these four features are selected. Double click on the mark to open the paragraph formatting box. This is a handy tip to remember when troubleshooting formatting issues. You may find "mystery" page breaks hiding here!

Word woes?

Email us at SKC@SusanChangConsulting.com (PC) and AlyssaWPhD@gmail.com (Mac).

The Medical Writers in the Playoff Season

With October comes a subtle shift in weather, riot of Fall colors and baseball playoffs. The playoffs signal a switch from the slow regular season to the exciting phase of baseball. It has the potential to generate Cinderella stories for years to come. Those who will win the World Series rings, will have their names etched in the baseball almanac.

In the October issue of Postscripts, Jennifer Reichert, PhD, CMPP, shares her story of making a similar leap into the playoffs. Jennifer has been practicing the art of publication planning for a while and like baseball playoffs, this year she finally decided to become a certified publication planning professional (CMPP). She calls the process of obtaining her certification stimulating and rewarding. Certification enhances credibility, proves value and signals competence in the chosen field.[1]

Since the practice of medical writing has many nuances, there are other certifications or "leagues of their own" where one can excel. The most popular ones are:

- Accredited in Public Relations (APR): Public relations
- Board of Editors in the Life Sciences (BELS): Editing
- Certified CME Professional (CCMEP): Continuing medical education
- Grant Professional Certification (GPC): Grant writing
- Regulatory Affairs Certification (RAC): Regulatory writing
- ELS professionals are certified to teach English as a Second Language (ESL), and having this certification signals mastery of the English language.

At present, medical writers do not have a common certification. But AMWA is working diligently to create a certification for all medical writers! In 1996, AMWA set up a task force that recommended further research into certifying medical communication professionals.[2] Since then, there has been open sessions, surveys and a report published in the AMWA Journal.[2]

Today, AMWA Certification is close to reality. AMWA plans to launch a manual in 2014 with the first examination in 2015.[3] The details are posted at www.amwa.org/certification.

The AMWA certification will target core competencies that will define who we are as a medical writer.[2] So, let the playoffs of medical writing begin.

— *Ajay K Malik, PhD*
ajay@amwa-pacsw.org

References:

1. Alexander L. Are We Certifiable? *The AMWA Journal Blog*. Sept 12, 2011. http://amwajournal.blogspot.com/2011/09/are-we-certifiable.html/. Accessed September 25, 2013.
2. Gegeny TP, Klein KP. AMWA's Medical Writing Certification Initiative: Where Are We Now? *AMWA J*. 2012;27(4):184-187.
3. AMWA Certification [webpage].American Medical Writers Association Website. http://www.amwa.org/certification/. Accessed September 25, 2013.

October Career Corner — Get Moving!

By Irene Yau, PhD, Allergan, Inc.

Although we may be inclined to be less active as summer comes to an end, it's important to remain active. Forgetting for a moment the extra pounds that come with the approaching holiday season, exercising can also be beneficial for our career. Research has shown that exercise improves the mood, increases energy, and can increase productivity.

Energy Levels: One study found that energy levels in participants were increased by 20% and fatigue levels were decreased by 65% with mild exercise[1].

Job Performance: A study conducted at the University of Bristol, England found that after exercising, workers self-reported better time management and improved mental sharpness[2].

Job Productivity: Another study assessing work productivity assigned employees into three groups: 1) mandatory activity 2.5hours/week during work hours 2) Same 2.5 hours reduction in work hours but no mandatory activity 3) Regular work hours with no exercise program[3]. Researchers found that Group 1 with mandatory activity had decreased work absences due to sick days and had self-rated increased work productivity.

Tim Cook, President Barack Obama, and Madeleine Albright, who can leg press 450 pounds, are among the successful people who have made exercise a part of their routine. Having an exercise routine does not mean training for triathlons or having P90X workout sessions. Even a little movement a day can go a long way. According to NIH researcher Dr. Steven Moore, just 10 minutes of low intensity exercise (such as walking) per day was associated with a 2 year increase in lifespan[4].

Tips for getting exercise at work:

- Do a mid-day walk –walk around the community during your lunch hour
- Use your work gym
- Inquire if your work provides any discounts to gym membership
- Grab a coworker and join a gym together – some gyms provide discounts for people joining together
- Use the stairs instead of the elevator
- Walking Meeting – why not try walking outside around the building with your colleague the next time you're discuss work matters.
- Start a "Biggest Loser" competition among your department and see who can lose the most weight in a given amount of time.

References:

1. Puetz TW, Flowers SS, and O'Conner PJ. A Randomized Controlled Trial of the Effect of Aerobic Exercise Training on Feelings of Energy and Fatigue in Sedentary Young Adults with Persistent Fatigue. *Psychother Psychosom* 2008;77:167–174.

2. McKenna J. & Coulson J. (In press). How does exercising at work influence work performance? A randomised cross-over trial. *Medicine and Science in Sports and Exercise* 2005;37:5 (suppt).

3. Ulrica von Thiele Schwarz, Henna Hasson. Employee Self-rated Productivity and Objective Organizational Production Levels. *Journal of Occupational and Environmental Medicine* 2011;53(8):838.

4. Don't Just Sit There! Move for your Health. *NIH News in Health*, December 2012

OCTOBER JOB LISTING SYNOPSIS

Associate Manager, Medical Information Services
Avinar Pharmaceuticals

Director Of Medical Writing and Publications
Spectrum Pharmaceuticals

Medical Writer – Promotional Activities
Arbor Scientia

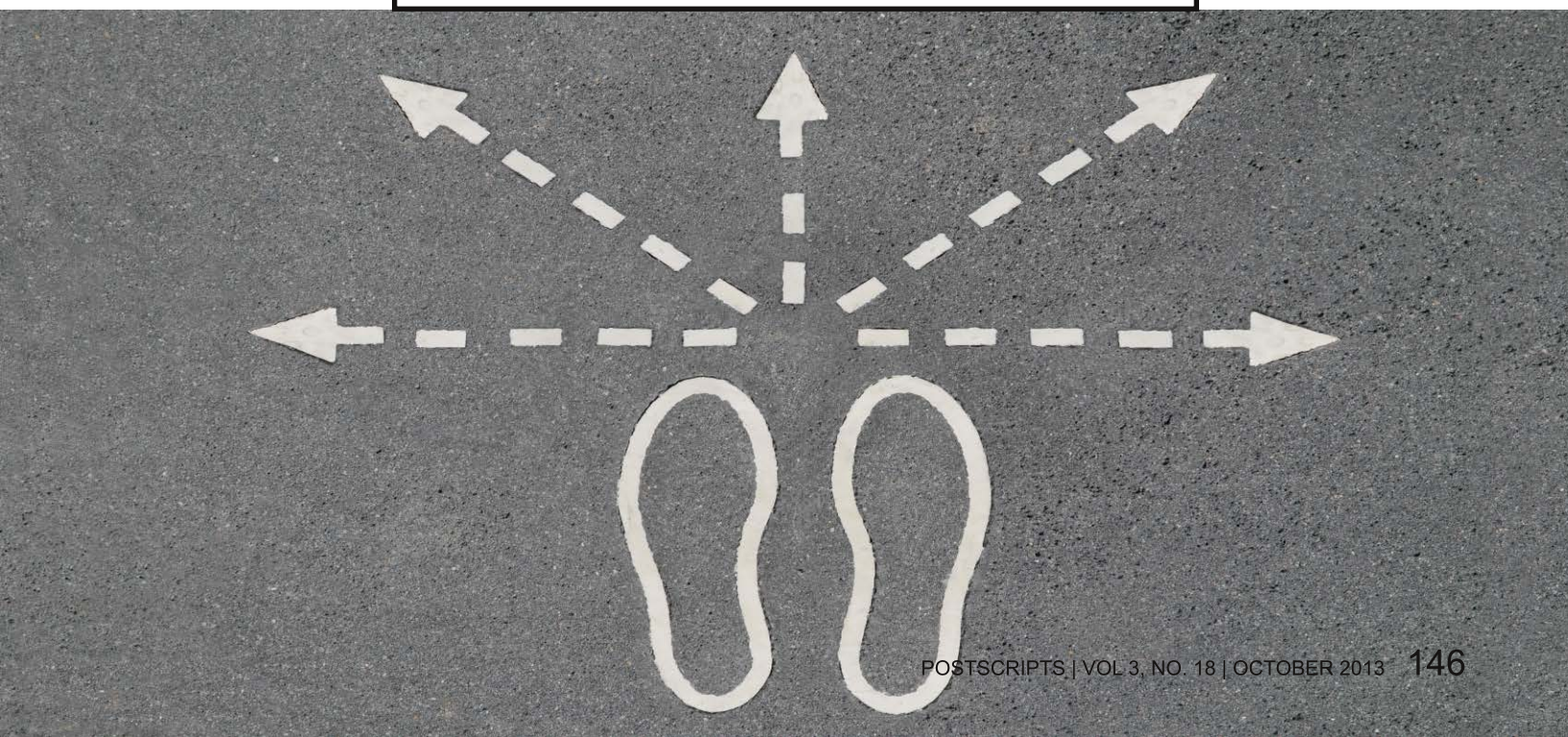
Science & Development Writer
Salk Institute for Biological Sciences

Science Writer/Media Liaison
Scripps Research Institute

As a reminder, Job Listings are available for current, interested members and are available through the following ways:

- Job openings are sent out on a ~monthly basis through the jobs mailing list
- Job listings will be posted periodically through our LinkedIn SubGroup, AMWA Pacific Southwest Chapter, so be sure to join the group

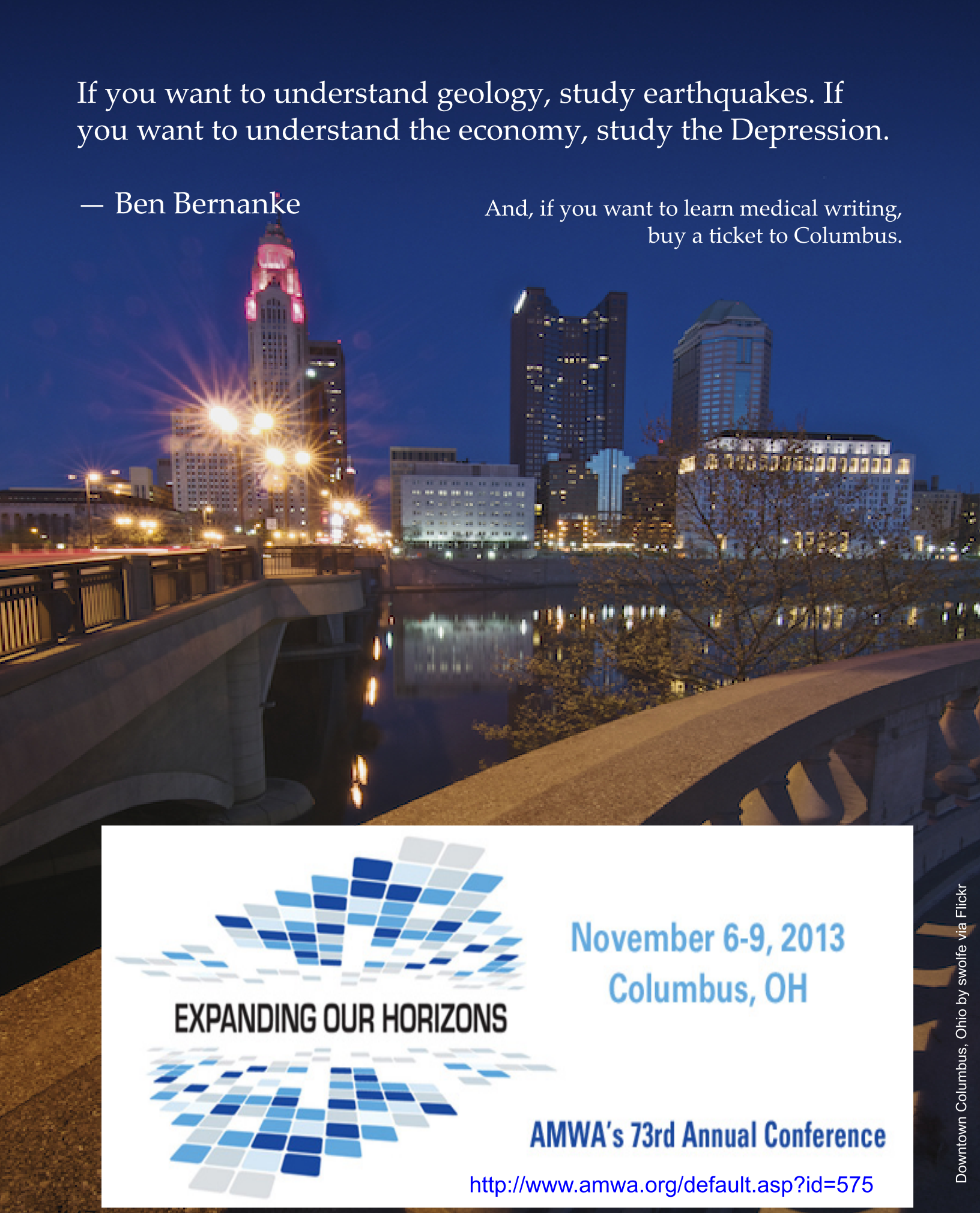
Please e-mail employment-coordinator@amwa-pacsw.org if you'd like to share any job leads with the group and it will be added to the job listings.



If you want to understand geology, study earthquakes. If you want to understand the economy, study the Depression.

— Ben Bernanke

And, if you want to learn medical writing, buy a ticket to Columbus.



EXPANDING OUR HORIZONS

November 6-9, 2013
Columbus, OH

AMWA's 73rd Annual Conference

http://www.amwa.org/default.asp?id=575

Downtown Columbus, Ohio by swolfe via Flickr

Safety Sentinels: Pharmacovigilance Issues and News

By Ellen Klepack, PharmD

This month's column will feature new label updates for extended release and long acting opioid analgesics.

Misuse, addiction, abuse and deaths due to overdose of extended release and long acting (ER/LA) opioid analgesics have steadily increased over the last decade. According to the CDC, 4,030 deaths involving opioids occurred in the United States in 1999, with that number rising to 15,597 and to 16,651 in 2009 and 2010 respectively.[1] Additionally, the incidence of neonates born to women taking opioids that experience neonatal opioid withdrawal syndrome (NOWS) has also increased. According to one study, between 2000 and 2009, the rate of neonatal abstinence syndrome, defined as a group of problems that occurs in newborns exposed to addictive illegal or prescription drugs while in the mother's womb, increased from 1.20 (95% CI, 1.04-1.37) to 3.39 (95% CI, 3.12-3.67) per 1000 hospital births per year (P for trend <.001).[2] This same study also showed a concurrent increase over the same time period in mothers diagnosed as dependent or using opioids at the time of delivery (1.19 [95% CI, 1.01-1.35] to 5.63 [95% CI, 4.40 to 6.71] per 1000 hospital births per year [P for trend <.001]). In an effort to curb these trends, FDA announced on September 10, 2013 that it will require class wide label changes for ER/LA opioids and new postmarketing studies from ER/LA opioid drug sponsors.[3] Updates to the ER/LA opioid analgesic Risk Evaluation and Mitigation Strategy (REMS) will follow the finalized label changes.

Updated Drug indication

Currently, ER/LA opioids are approved to treat moderate to severe chronic pain. The new language will indicate that they are approved in the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.[3,4] This language has been strengthened to clarify the intended treatment population and discourage the use of these drugs on an as needed basis.

New Boxed warning

The new warning will caution that infants born to women requiring opioid therapy while pregnant may require treatment for NOWS. This condition can be life threatening and require management according to protocols developed by neonatology experts.[3,4]

Postmarketing Studies

Postmarketing studies will be conducted to obtain additional data on the risks of misuse, abuse, addiction, hyperalgesia, overdose and deaths associated with the long term use of ER/LA opioids. According FDA's timelines, data are scheduled to be available in 2015-2017 from the following planned studies: (1) A validation of measures of adverse events and coded medical terms associated with the used of ER/LA opioids. (2) Studies designed to define and validate "doctor/pharmacy" shopping suggestive of misuse, abuse and/or addiction. (3) An assessment of risk of hyperalgesia and development of tolerance following long term use (at least one year) of ER/LA opioid analgesics.[4] Data are scheduled to be available from the following studies in 2018: (1) Studies to quantitate the incidence of misuse, abuse, addiction, overdose and death associated with long term use of opioids in chronic pain. (2) Studies that will assess the effect of product

(continued on next page)

formulation, dose, duration of use, prescriber specialty, indication, patient clinical factors and other risk factors on misuse, abuse, addiction overdose and death.[4]

Sources

1. US Food and Drug Administration. Opioids drive continued increase in drug overdose deaths: drug overdose deaths increase for 11th consecutive year. http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html. February 20, 2013. Accessed September 23, 2013.
2. Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. JAMA. 2012;(18):1934-40. Doi:10.1001/jama.2012.3951.
3. US Food and Drug Administration. FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm. Published September 10, 2013. Accessed September 23, 2013.
4. US Food and Drug Administration. LABELING SUPPLEMENT AND PMR REQUIRED. http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf. Accessed September 23, 2013.

Jimson Weed

Jimson Weed by Georgia O'Keeffe.1932. Oil on canvas, 48 x 40 inches.
Georgia O'Keeffe Museum, Santa Fe, NM.